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(71) Applicant(s)
John Francis Cockburn
51 Holyoake Walk, EALING, London, W5 1QN, United Kingdom

(72) Inventor(s)
John Francis Cockburn

(74) Agent and/or Address for Service
Kenneth Graham Johnston
5 Mornington Road, WOODFORD GREEN, Essex, IG8 0TU, United Kingdom

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A61M 25/06

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A5R RGBB RGN

(56) Documents Cited

GB 2262238 A	GB 2255282 A	GB 2044107 A
GB 1321205 A	EP 0278186 A1	EP 0127781 A2
WO 92/05816 A1	US 5360416 A	US 4838877 A
US 4790830 A	US 4413993 A	US 4411657 A

(58) Field of Search
UK CL (Edition N) A5R RGBB RGN
INT CL[6] A61M 5/32 25/06
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(54) **Needle with occlusion-preventing aperture**

(57) The needle 30 has one or more apertures 32A at its distal end which are located and dimensioned to prevent occlusion by body tissue. The aperture may be formed by a convexly sided, transverse channel cut into the needle wall or may face rearwardly. Alternatively, a plurality of spaced, longitudinal slits or circular apertures may be provided by laser perforation. The needle may be associated with an outer cutting sheath 34 housing a trocar 21 for use in ultrasound imaging. In further embodiments, the needle may constitute the stylet of an aspiration biopsy needle (Fig.8) or a needle assembly may comprise a stylet within a cannula, the stylet having an expanded distal tip of cross-section complimentary to that of the cannula bore so as to prevent occlusion of the cannula end by tissue (Fig.7).

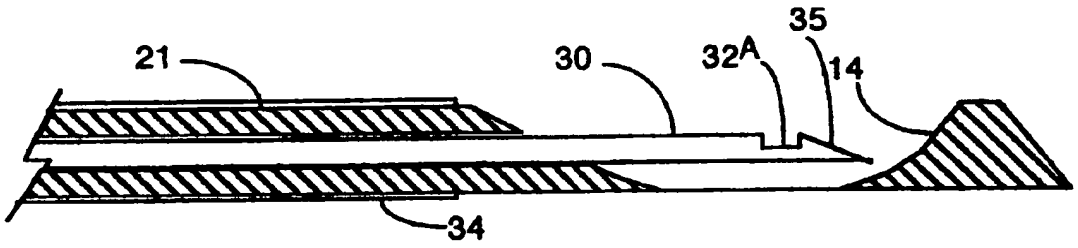

Fig. 3

GB 2 298 368 A

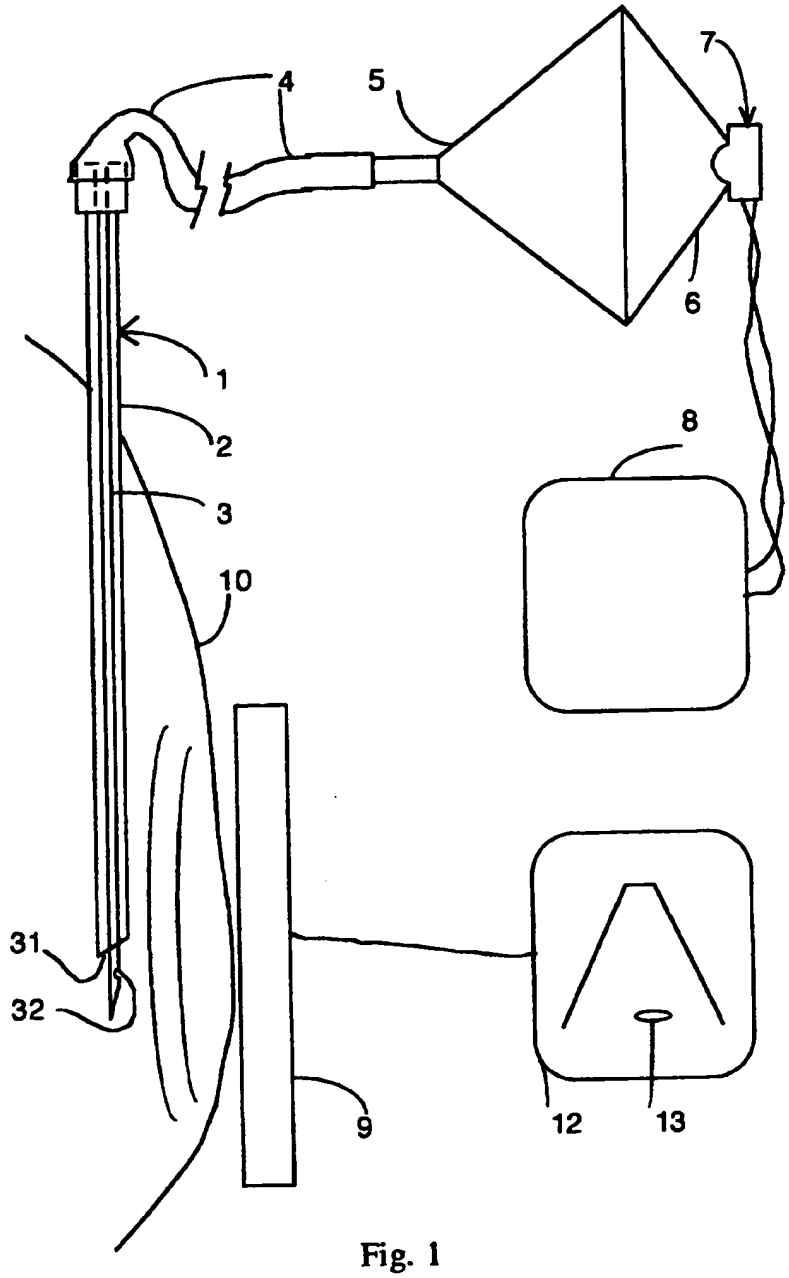

Fig. 1

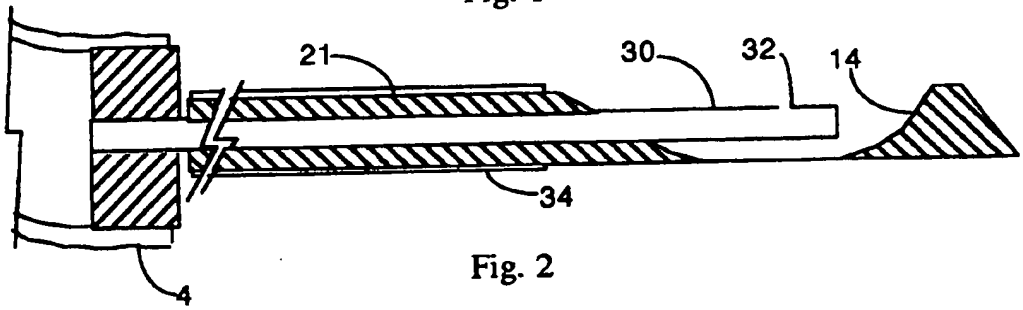

Fig. 2

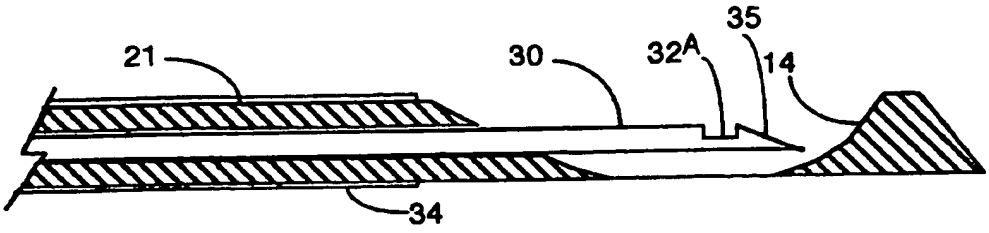

Fig. 3

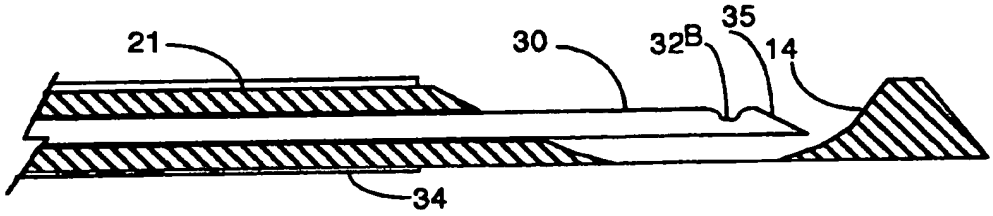

Fig. 4

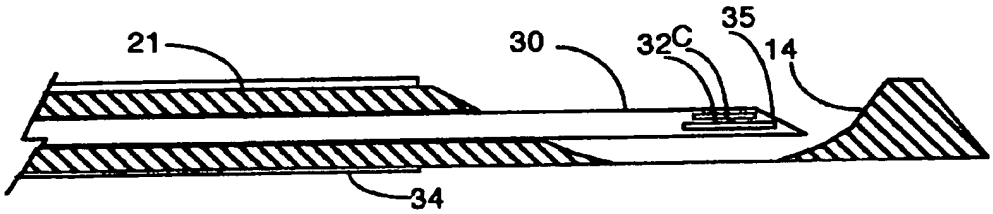

Fig. 5

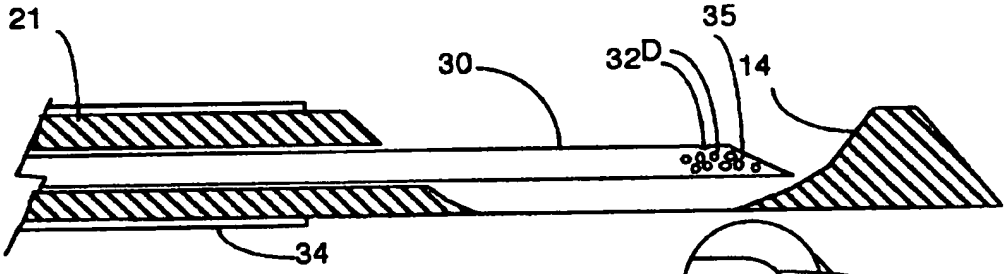

Fig. 6

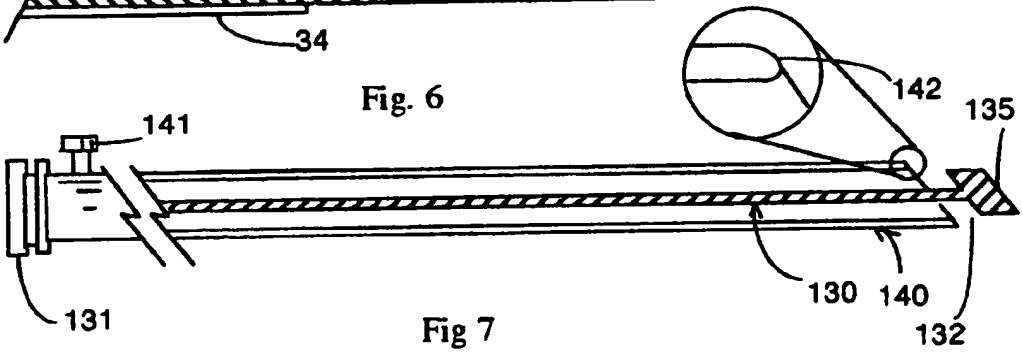

Fig 7

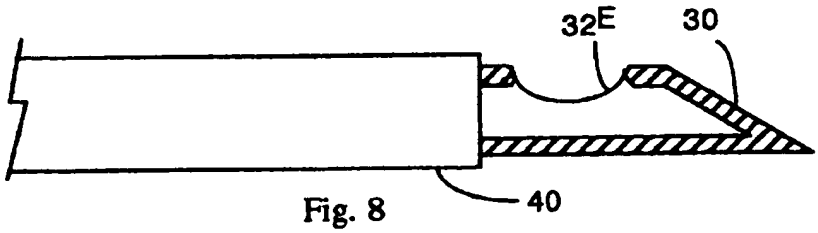

Fig. 8

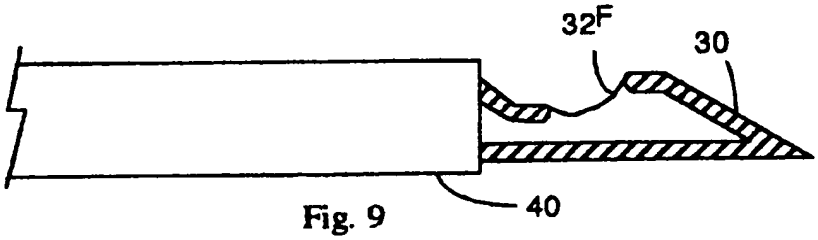

Fig. 9

Medical needle for use in ultrasound imaging

The present invention relates to a hollow medical needle for use in ultrasonic imaging.

The theory of ultrasonic transmission in biopsy needles is discussed in ULTRASONICS Vol. 26, No. 1, 1988 pp 27 to 30.

US 3,556,079 (Omizo) discloses a medical apparatus comprising a tubular needle within which is mounted an ultrasonic transducer which may be a transmitter, a receiver or a combined transmitter and receiver. This transducer is coupled to saline solution within the needle and transmits and/or detects ultrasound at considerable distances through body tissue at a frequency of e.g. 5MHz which is subsequently reflected off e.g. flowing blood in a blood vessel and shifted in frequency according to the Doppler equation. If the transducer in the needle is a transmitter only, then an external ultrasound receiver is arranged to detect the reflected Doppler-shifted ultrasound which is demodulated to generate an audio signal whose amplitude is a maximum when the needle is directed at the blood vessel. However the above arrangement merely enables the position of the blood vessel or other target to be detected and does not enable the position of the needle to be detected. It could not, for example, be used to direct a needle towards a portion of diseased static tissue. Furthermore it is not an imaging system.

Ultrasound imaging utilises the principle of sound reflectivity in order to form images of body organs. These images are displayed on the monitor in grey-scale. Some ultrasound machines also incorporate the principle of Doppler frequency shift which allows moving objects eg red blood cells in a blood vessel to be imaged. Such vessels can then be assigned a colour according to the direction of movement within them, and they appear in colour against the grey-scale background of their environs.

It is often desirable to form such an image during treatment with an aspiration or a biopsy needle and it has been found difficult to produce a clearly defined image of the needle by this technique. It has been proposed to apply a transverse vibration to the needle in order to overcome this problem but this does not result in a clear image of the needle tip.

Co-pending patent application GB 9503548 (from which the present application claims priority) discloses and claims a medical apparatus comprising a tubular needle which is adapted for insertion into body tissue, the needle being provided with a transducer which is substantially mechanically isolated from the needle and coupled to a fluid column within the needle, the transducer being arranged to generate a longitudinal oscillation of said fluid column at a sub-ultrasonic (preferably audio) frequency which enhances the visibility of the region of the needle tip to Doppler ultrasound imaging.

The above application discloses an apparatus in which the transducer is remote from the needle and is coupled to the needle by a flexible tube which contains a further fluid column (preferably an air column) coupled to the transducer. The above apparatus was subsequently described by the present applicant in the May 1995 issue of *Radiology* . In a preferred embodiment disclosed in the above patent application, the needle comprises a tubular stylet, the stylet being located within a cannula or trocar and said transducer being coupled to a fluid column within the stylet and substantially isolated from the stylet.

The present invention provides a hollow medical needle which has an aperture at its distal end which communicates with its bore, the aperture being located and dimensioned to substantially prevent its occlusion by body tissue in use.

The invention also provides a needle assembly comprising a stylet within a cannula, the stylet having an expanded distal tip which tip has a transverse cross-section generally complementary to that of the bore of the cannula so as to substantially prevent the occlusion by body tissue of the distal end of the cannula in use, the stylet being advanceable relative to the cannula to define a radial aperture between said tip and the distal end of the cannula which communicates with the bore of the cannula.

For the avoidance of doubt, neither the hollow medical needle discosed in my earlier UK patent application GB 9404863.4 which has a radial aperture at its proximal end and an open tubular distal end through which a solid stylet extends, nor the needle assembly disclosed in that UK patent application in which the cross-section of the distal tip of the stylet is not generally complementary to that of the bore of the cannula is considered to be within the scope of the present invention.

In a preferred embodiment of the present invention the aperture is a radial aperture formed in a cylindrical wall of the needle. However it is also envisaged that the aperture may face rearwardly.

The needle of the present invention may for example comprise a hollow stylet in

which said aperture is formed, and may optionally include a cannula or trocar in which the stylet is located.

Preferably the aperture has a non-cutting external edge region, which may for example be defined by a convex transition region between the forward and/or rear region of the aperture and the adjacent forward and/or rear external surface of the needle wall.

Desirably the smallest dimension of the or each said aperture is no greater than 2mm, preferably no greater than 1 mm, more preferably no greater than 0.5mm.

The medical needle of the present invention is particularly but not exclusively for use in the above-described apparatus of GB 9503548.1. For example the needle of the invention (particularly when in the form of a stylet) may alternatively be used to introduce alcohol from its aperture into a tumour to necrose the tumour.

Preferred embodiments of the invention are described below by way of example only with reference to the accompanying drawings, wherein:

Figure 1 is a diagrammatic representation of an ultrasonic imaging apparatus for use with a stylet in accordance with the invention;

Figure 2 is a longitudinal cross-section of a needle in accordance with the invention for use in the arrangement of Figure 1;

Figure 3 is a longitudinal cross-section of another needle in accordance with the invention for use in the arrangement of Figure 1;

Figure 4 is a longitudinal cross-section of another needle in accordance with the invention for use in the arrangement of Figure 1;

Figure 5 is a longitudinal cross-section of another needle in accordance with the invention for use in the arrangement of Figure 1;

Figure 6 is a longitudinal cross-section of another needle in accordance with the invention for use in the arrangement of Figure 1;

Figure 7 is a side elevation, partly in cross-section of a needle assembly in accordance with the invention;

Figure 8 is a side elevation, partly in cross-section of an aspiration biopsy needle

assembly in accordance with the invention, and

Figure 9 is a side elevation, partly in cross-section of a further aspiration biopsy needle assembly in accordance with the invention.

Referring to Figure 1, which is a purely diagrammatic representation, a hollow needle 1 is shown inserted into body tissue 10. The needle comprises a 22 gauge tubular cannula 2 having an outside diameter of 0.711mm (0.028") and housing a stylet 3 of 0.457 mm (0.018") diameter within the cannula. The tip of the stylet projects about 2mm beyond the tip 31 of the cannula. The stylet is hollow and has an eccentric opening 32 immediately adjacent to its closed bevelled tip. The eccentric opening, which protrudes beyond the end of the 22 gauge housing cannula, allows the oscillating air column to deliver movement to adjacent tissue but is shaped and dimensioned to minimise the possibility of body tissue entering the stylet and occluding it. This arrangement allows the tip of the stylet to be rendered visible to Doppler ultrasound during the insertion of the needle through tissue. 8mm flexible pressure tubing 4 connects the hollow stylet with the neck of a funnel member 5 as shown. The mouth of funnel member 5 is coupled in an airtight manner to a moving coil loudspeaker 7 whose diaphragm 6 is driven by a signal from a signal generator 8.

Preferably the signal , which may be a pulsed or an oscillating signal, has a period of 0.03s to 0.001s . More preferably the signal has a sine, square or triangular waveform of frequency 333Hz to 1kHz (ideally 400 to 800Hz e.g. 600Hz) and a power of a few (e.g. 100) mW.

The body tissue is insonated with an ultrasonic beam 11 by a Doppler ultrasound imager 9, which may for example be an Acuson 128 XP10 imager. An image 13 of the needle tip 31 is formed on a screen 12 of the imager.

The optimum frequency of the longitudinal oscillation generated by the transducer of the needle arrangement will depend on the Colour Doppler ultrasonic imager with which it is being used, in particular on the velocity range detectable by the imager. In a typical Colour Doppler ultrasonic imager the minimum detectable velocity will be of the order of ±0.001m/s and a maximum velocity of about ±3.8m/s, with a more usual range being from ±0.02m/s to ±0.6m/s. Accordingly it is believed that the frequency and amplitude of oscillation should be such that the maximum velocity is within the above ranges. With conveniently achievable amplitudes of oscillation, it is believed that the most useful frequencies will be in the audio range i.e. 20Hz to 20 kHz but the invention is by no means limited to stylets suitable for the above ranges.

Referring now to Figure 2, the needle arrangement shown is designed to prevent occlusion of the oscillating fluid column during insertion into the body tissue and comprises a tubular outer cutting sheath 34 housing a trocar 21. Trocar 21 has a recess 14 at its distal end which exposes a retractable tubular stylet 30 which has a radially directed aperture 32 adjacent its forward (distal) tip. An inclined surface 35 defines this tip. The bore of stylet 30 communicates with the funnel arrangement shown in Figure 1 via flexible tubing 4 and consequently the Doppler signal is emitted at aperture 32 throughout the insertion and enables the precise position of the tip portion of the needle arrangement to be detected continuously. In a variant, two, three or more smaller apertures regularly circumferentially distributed about the forward region (e.g. the region up to 10 mm from the tip) of the stylet may be substituted for the single aperture 32 in order to increase the strength of the stylet.

In use, first the trocar 21 is advanced (i.e. to the right in Figure 2) together with the stylet 30, the latter having its aperture 32 located in the recess 14 as shown and the outer cutting sheath being retracted as shown. When the recess 14 has been advanced to the required position, as determined with the aid of the Doppler ultrasound image of the stylet tip region, the stylet 30 is withdrawn from the trocar 21 to allow tissue to fill the recess 14 and outer cutting sheath 34 is advanced (i.e. from left to right relative to Figure 2) over the trocar to cut off the tissue lying in recess 14. The resulting tissue sample can then be extracted. In this manner a tissue sample (e.g. of a liver lesion) can be taken from an accurately known region of the tissue.

The needle assemblies of Figures 3 to 6 are similar to that of Figure 2 except that the design of the forward tip of the stylet is varied. Accordingly, corresponding parts are denoted by the same reference numerals.

In the arrangement shown in Figure 3, the aperture 32^A is defined by a channel of rectangular cross-section cut in the upper surface of the wall of the hollow stylet 30.

In the needle arrangement shown in Figure 4, the sides of the channel are convex and the base if the channel is concave, so that the transverse cross-section of the channel has a gradual convex transition with the adjacent forward portion of the exterior surface of the cylindrical wall. The resulting aperture 32^B is therefore less likely to cut tissue as it is advanced.

In the needle arrangement shown in Figure 5, the aperture is in the form of a plurality (e.g. 3) of longitudinal slits 32^C of length 5 mm and width 100 micrometers which are spaced regularly around the forward region of the circumference of the stylet.

In the arrangement shown in Figure 6, a multiplicity (e.g. 5 or more) of circular apertures 32^D are provided. They are suitably of diameter 100 micrometers and may be formed by laser beam perforation of the stylet wall, for example. In a particularly preferred embodiment there are 15 apertures of diameter 127 micrometres (0.005 inches) formed by laser beam perforation of the stylet wall.

The needle assembly shown in Figure 7 comprises a solid stylet 130 having an expanded distal tip of circular transverse cross-section with an inclined flat face 135, the face 135 having a cutting edge at its periphery, and a cannula 140 whose cylindrical bore is of slightly greater diameter than that of the distal tip of the stylet. The outer edge region 142 of the mouth of the cannula is rounded to prevent it from cutting tissue and a radial aperture 132 is defined by the gap between the mouth of the cannula and the distal tip of the stylet. The proximal end of the cannula 140 has a radial port 141 which communicates with its bore and can be attached to the flexible tubing 4 of the apparatus shown in Figure 1 to provide sub-ultrasonic emission from aperture 132. The proximal end 131 of the stylet 130 protrudes from and, in the position shown in Figure 7, seals the proximal end of the cannula 140 but can be retracted to withdraw the stylet from the cannula after the tip region of the assembly has been located by the Doppler ultrasound apparatus of Figure 1.

The needle arrangement shown in Figure 8 comprises an aspiration biopsy (Chiba) needle 40 and a hollow tubular stylet 30 with a non-cutting aperture 32^E which is housed within the needle 40. The periphery of the aperture 32^E is smoothly rounded to prevent occlusion by tissue and the bore of the stylet is connected to the flexible tubing 4 of the apparatus shown in Figure 1 to provide sub-ultrasonic emission from aperture 32^E.

The needle arrangement shown in Figure 9 comprises an aspiration biopsy (Chiba) needle 40 and a hollow tubular stylet 30 with a non-cutting aperture 32^F which is housed within the needle 40. The periphery of the aperture 32^F is smoothly rounded and faces rearwardly to prevent occlusion by tissue and the bore of the stylet is connected to the flexible tubing 4 of the apparatus shown in Figure 1 to provide sub-ultrasonic emission from aperture 32^F.

In all the arrangements illustrated in the drawings, the stylet, cannula and trocar (if used) as well as the flexible tubing are sterilised and may be disposable.

The invention also extends to every novel combination or sub-combination disclosed herein.

Claims

1. A hollow medical needle which has an aperture at its distal end which communicates with its bore and is located and dimensioned to substantially prevent its occlusion by body tissue in use.

2. A needle as claimed in claim 1 wherein said aperture is a radial aperture.

3. A needle as claimed in claim 1 or claim 2 wherein said aperture is formed by a transverse channel cut into a cylindrical wall of said needle.

4. A needle as claimed in claim 3 wherein the transverse cross-section of said channel has a gradual convex transition with the adjacent forward portion of the exterior surface of said cylindrical wall.

5. A needle as claimed in claim 4 wherein said transverse cross-section has a concave base portion.

6. A needle as claimed in claim 1 or claim 2 wherein a plurality of such apertures are formed in said distal end.

7. A needle as claimed in any preceding claim wherein the smallest dimension of the or each said aperture is no greater than 2 mm.

8. A needle as claimed in claim 6 wherein said apertures are obtainable by laser perforation of the needle wall.

9. A needle as claimed in any of claims 1, 2, 6 and 7 wherein one or more such apertures are in the form of longitudinally extending slits in the stylet wall.

10. A needle as claimed in any preceding claim which is sterilised.

11. A needle as claimed in any preceding claim which is a stylet.

12. A needle assembly comprising a stylet as claimed in claim 9 and a cannula or trocar in which said stylet is located.

13. A needle assembly comprising a stylet within a cannula, the stylet having an expanded distal tip which tip has a transverse cross-section generally complementary to that of the bore of the cannula so as to substantially prevent the occlusion by body tissue of the distal end of the cannula in use, the stylet being advanceable relative to

the cannula to define a radial aperture between said tip and the distal end of the cannula which communicates with the bore of the cannula.

14. A needle assembly or a stylet substantially as described hereinabove with reference to any of Figures 2 to 9 of the accompanying drawings.

15. A medical apparatus comprising a tubular needle which is adapted for insertion into body tissue, the needle being provided with a transducer which is substantially mechanically isolated from the needle and coupled to a fluid column within the needle, the transducer being arranged to generate a longitudinal oscillation of said fluid column at a sub-ultrasonic frequency which enhances the visibility of the region of the needle tip to Doppler ultrasound imaging, wherein the transducer is remote from the needle and is coupled to the needle by a flexible tube which contains a further fluid column coupled to the transducer and the needle comprises a tubular stylet as claimed in claim 11, the stylet being located within a cannula or trocar and said transducer being coupled to a fluid column within the stylet and substantially isolated from the stylet.

16. A medical apparatus as claimed in claim 15 wherein said stylet is substantially as described hereinabove with reference to any of Figures 3 to 6 or 8 and 9 of the accompanying drawings.

17. A medical apparatus comprising a needle assembly as claimed in claim 13 which is adapted for insertion into body tissue, the needle assembly being provided with a transducer which is substantially mechanically isolated from the needle assembly and coupled to a fluid column within the cannula thereof, the transducer being arranged to generate a longitudinal oscillation of said fluid column at a sub-ultrasonic frequency which enhances the visibility of the region of the tip of the needle assembly to Doppler ultrasound imaging, wherein the transducer is remote from the needle assembly and is coupled to the bore of the cannula by a flexible tube which contains a further fluid column coupled to the transducer.

18. A medical apparatus as claimed in claim 17 wherein said needle assembly is substantially as described hereinabove with reference to Figure 7 of the accompanying drawings.

9

Patents Act 1977 Examiner's report to the Comptroller under Section 17 (The Search report)	Application number GB 9518579.9
Relevant Technical Fields (i) UK Cl (Ed.N) A5R (RGBB, RGN) (ii) Int Cl (Ed.6) A61M 5/32, 25/06	Search Examiner L V THOMAS Date of completion of Search 13 DECEMBER 1995
Databases (see below) (i) UK Patent Office collections of GB, EP, WO and US patent specifications. (ii) ONLINE: WPI	Documents considered relevant following a search in respect f Claims :- 1-12, 14(PART), 15, 16

Categories of documents

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A:	Document indicating technological background and/or state of the art.	**&:**	Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
X	GB 2262238 A	(AGLAN ET AL) see page 2, lines 9-15 and page 7, lines 3-16	1, 2
X	GB 2255282 A	(AL-SAM) see whole document	1, 2, 6, 7
X	GB 2044107 A	(TERUMO CORPORATION) see page 1, line 124 - page 2, line 20	1, 2, 6, 7, 11, 12
X	GB 1321205	(DOW CORNING) see page 1, lines 41-78 and page 2, lines 12-21	1-3, 9
X	EP 0278186 A1	(SOFIC) see column 1, lines 23-40, column 2, lines 21-43 and column 3, lines 10-15	1-3, 9
X	EP 0127781 A2	(BECTON, DICKINSON) see page 6, lines 13-25 and page 12, lines 1-6	1-3, 9
X	WO 92/05816 A1	(SULZER) see WPI Abstract Accession No 92-150603/18	1
X	US 5360416	(AUSHERMAN ET AL) see column 2, lines 9-36 and column 3, lines 11-63	1-3, 9

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